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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/798,064

03/11/2004

Susanne Arney

10-18-4

5680

7590

11/19/2009

Michael J. Urbano
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EXAMINER

PELLEGRINO, BRIAN E

ART UNIT

PAPER NUMBER

3738

MAIL DATE

DELIVERY MODE

11/19/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--|-------------------------------------|--|
| Office Action Summary | Application No. 10/798,064 | Applicant(s) ARNEY ET AL. | |
| | Examiner Brian E. Pellegrino | Art Unit 3738 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

In view of the Appeal Brief filed on 8/13/09, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/Corrine M McDermott/

Supervisory Patent Examiner, Art Unit 3738

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-8,12,13,18-20 are rejected under 35 U.S.C. 103(a) as obvious over Bailey et al. (WO 02/64019) in view of Karwoski et al. (4718907). Bailey et al. disclose the stent is made of metal material (page 16). Bailey additionally discloses a region of the stent has a plurality of microstructures that can include electronic components, page 5, lines 3-11. Another stent is also disclosed that describes an array of microstructures or grooves and hydrophobicity can be controlled in dynamic fashion, page 10, lines 17-33. The cellular response and its effect on the microstructure clearly effects hydrophobicity. Bailey et al. also disclose chemically active substances adhered to the stent and that a voltage or energy can be applied to the device from an ex vivo source, page 23, lines 5-15. Bailey additionally discloses controlled release of substances by electrical energy, page 23, lines 23-31. Please note that "isolated zones" is an arbitrary limitation and just like an elongate object, i.e. a stent has arbitrary ends, zones can be said to be present as established in Figs. 1 and 3 since the means for applying electrical

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energy is spaced about the surface. Also the presence of grooves can be said to clearly establish isolated surface zones. Additionally fluid is capable of being suspended over the microstructures in a first state and then penetrates between the microstructures in a second state. It is also evident as seen in Fig. 4, that medicinal material is in the microstructures. However, Bailey does not explicitly state the surface is hydrophobic with a contact angle greater than 90° when a body fluid drop contacts it. Karwoski et al. teach to coat inner surfaces of prostheses with a coating that provides a hydrophobicity that a drop of body fluid will have a contact angle greater than 90° to give it a non-thrombogenic surface, col. 2, lines 61-68, col. 3, lines 1-3,13-18,58-61. It would have been obvious to one of ordinary skill in the art to coat the inner surface of the device of Bailey with the coating of Karwoski et al. to provide a hydrophobic surface to give a contact angle to fluid greater than 90° since such that it reduces thrombogenicity.

Claims 1,2,5-7,9-11 are rejected under 35 U.S.C. 103(a) as obvious over Momma et al. (2005/27350) in view of Karwoski et al. '907. Fig. 2 shows a stent body **42** that includes an array microstructures **38** and control device in the form of a membrane **46** to vary hydrophobicity. The array of microstructures include surfaces of exposed and having chemically active substances in two zones **52**, **54** adhered thereto capable of release at different times. Momma et al. disclose the stent is a metal and thus has a hydrophobic surface, paragraph 35. Momma additionally discloses the chemically active substances can be different, paragraphs 21,45. However, Momma does not explicitly state the surface is hydrophobic with a contact angle greater than 90° when any drop of fluid contacts it. Karwoski et al. is explained supra. It would have

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been obvious to one of ordinary skill in the art to coat an inner surface as taught by Karwoski et al. such that it has a contact angle to fluid greater than 90° on the inner side of the stent of Momma such that it is non-thrombogenic.

Claims 1,2,5-7,15-17 are rejected under 35 U.S.C. 103(a) as obvious over Shastri et al. (2004/115239) in view of Karwoski et al. '907. Shastri et al. disclose an implant having a plurality of fibers or particles of nanosize placed on its surface, paragraph 48,49. Shastri also discloses the nano-material can be silicon (paragraphs 41,52) a semiconductor material. Shastri additionally discloses the implant can be a stent, paragraph 54. The nanostructures have a size within the range of 4µm to 20nm, paragraph 69. Shastri discloses chemically active substances can be used on the device with control devices (polymer materials), paragraphs 75,79,82,84. These include cells that change the surface properties or hydrophobicity. Shastri discloses (paragraph 87) properties modified or controlled, including wettability that the Examiner interprets to affect the hydrophobicity. However, Shastri does not explicitly state the surface is hydrophobic with a contact angle greater than 90° when any drop of fluid contacts it. Karwoski et al. is explained above. It would have been obvious to one of ordinary skill in the art to coat an inner surface of the Shastri device to provide a hydrophobic surface having a contact angle to fluid greater than 90° as taught by Karwoski et al. such that it reduces thrombogenicity and reduces the likelihood of restenosis.

Claims 1,14 are rejected under 35 U.S.C. 103(a) as obvious over Oktay (2003/40791) in view of Karwoski et al. '907. Oktay shows (Fig. 10) a stent **1000** with an array of microstructures **1050,1060** on a region of the surface of the stent. Oktay

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discloses (paragraph 69) the stent structure is made of metal. Oktay further illustrates (11A-11C) the stent includes electrically controllable structures **1040** for latching the edges of the tubular body. However, Oktay does not explicitly state the surface is hydrophobic with a contact angle greater than 90° when any drop of fluid contacts it. Karwoski et al. is explained as before. It would have been obvious to one of ordinary skill in the art to coat an inner surface to be hydrophobic with a contact angle to fluid greater than 90° as taught by Karwoski et al. with the stent of Oktay such that it is provided with a non-thrombogenic surface.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bailey et al. (WO 02/64019) in view of Karwoski et al. '907 as applied to claim 19 above, and further in view of Momma et al. (2005/27350). Bailey et al. as modified with Karwoski et al. is explained supra. However, Bailey et al. in view of Karwoski fail to disclose different substances to be released into the implantation site. Momma et al. teach that different medicinal substances can be utilized to deliver to the implantation site for different purposes, paragraphs 21,45. It would have been obvious to one of ordinary skill in the art to incorporate different drugs on the stent as taught by Momma et al. in the stent of Bailey et al. modified with Karwoski et al. such that it provides multiple therapeutic capabilities to encounter the biological responses of the body.

Response to Arguments

Applicant's arguments, see Appeal Brief, filed 8/13/09, with respect to the rejection(s) of claim(s) 1-21 under 35 U.S.C. 102/103 have been fully considered and

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are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Karwoski et al. '907.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (9am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700
/Brian E Pellegrino/
Primary Examiner, Art Unit 3738